

# EXHIBIT A

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
ex rel. RONALD J. STRECK, et al.,	:	
	:	
Plaintiffs,	:	
v.	:	
	:	CIVIL ACTION NO. 08-5135
ALLERGAN, INC., et al.,	:	
	:	
Defendants.	:	

**STATEMENT OF INTEREST BY THE UNITED STATES OF AMERICA  
IN RESPONSE TO DEFENDANTS' MOTION TO DISMISS  
THE FOURTH AMENDED COMPLAINT**

The United States submits this Statement of Interest pursuant to 28 U.S.C. § 517 in response to statements made at oral argument concerning Defendants' motion to dismiss the Fourth Amended Complaint. This brief does not take a position on the merits of Defendants' motion or the merits of the qui tam relator's action. Rather, it addresses arguments about the Supreme Court's decision in Safeco Ins. Co. v. Burr, 551 U.S. 47 (2007) and the discussion of the scienter standard under the False Claims Act, 31 U.S.C. § 3729 et seq. ("FCA") that the government believes require clarification.

**I. The Government's Interest in This Case**

Although the United States declined to intervene in this action, because the rulings in the case affect the government's ability to bring future FCA cases, the government has a continuing interest in this case. The FCA is the government's principal tool for fighting fraud in government programs, and the government is thus concerned that the FCA be interpreted in a

manner consistent with its language and purposes. Furthermore, as the real party in interest, the government will receive the majority of any recovery that may be obtained.

## **II. The Supreme Court's Decision in Safeco Ins. Co. v. Burr is Not Dispositive and Knowledge and Falsity are Distinct Elements of FCA Liability**

At oral argument, defense counsel argued that the Supreme Court's decision in Safeco Ins. Co. v. Burr, 551 U.S. 47 (2007), was dispositive. The government disagrees with that characterization because the scienter standard at issue in Safeco differs from the scienter standard of the FCA.

In Safeco, plaintiffs sued for violations of the Fair Credit Reporting Act, where the scienter standard of "willfully fails to comply" is akin to recklessness. Id. at 57. In contrast, the FCA imposes liability not only for "reckless disregard", but also for "deliberate ignorance." As many courts have recognized, the FCA knowledge standard was expressly "designed to address the problem of the 'ostrich-like' refusal to learn of information which an individual, in the exercise of prudent judgment, had reason to know." Lamb Eng'g & Constr. Co. v. United States, 58 Fed Cl. 106, 110 (Ct. Fed. Cl. 2003). The deliberate ignorance language makes clear that it is a defendant's own knowledge and actions that are the subject of the scienter inquiry, and that Congress did not intend for a defendant to ignore its obligations, bury its head in the sand, and escape liability by relying on arguments that are later raised during litigation. See S. Rep. No. 99-345, at 21 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5286.

This principle is pertinent in FCA cases where the defendants are enrolled in government health programs. Contractors doing business with the government are expected to take reasonable steps to verify that their interpretation of regulations and contractual terms is correct before submitting claims for payment. See Rep. No. 99-345, at 15-16, reprinted in 1986

U.S.C.C.A.N. 5280-81 (explaining that official who refused “to learn of information which an individual, in the exercise of prudent judgment, had reason to know” will be considered knowing under the FCA). This is consistent with the general understanding that a person participating in a regulated government program, and seeking federal funds, has a duty to inquire and clarify ambiguities in governing regulations or contracts. See e.g., Heckler v. Community Health Svs., 467 U.S. 51, 64 (1984) (reasoning that participant in Medicare program “had a duty to familiarize itself with the legal requirements for cost reimbursement” and to seek clarification by the agency of ambiguities interpreting regulations); Maintenance Engineers, Inc. v. United States, 21 Cl. Ct. 553, 559 (U.S. Cl. Ct. 1990) (holding that bidder on government contract must seek clarification of contract term if ambiguity would be apparent to a reasonably prudent contractor). Thus, in an FCA case, evidence about what steps a defendant took to ascertain the government’s construction of an allegedly ambiguous regulation or contract would be pertinent in determining whether the defendant acted “knowingly.”

Defendants argue that the term Average Manufacturer’s Price (“AMP”) was ambiguous or unclear to them, and that they made a reasonable interpretation of that term. Ambiguity in a federal regulation or government contract, however, does not preclude a finding that a submission to the government was false within the meaning of the FCA. Under the plain language of the FCA, the question whether a defendant “knowingly” submitted a false claim or statement is distinct from the question whether the submission was false. That latter question - falsity - is a legal determination to be made by the district court, employing normal tools of construction to determine whether statements or claims were objectively false. And while the

existence of regulatory ambiguity may be relevant to a defendant's scienter,<sup>1</sup> it is irrelevant to whether a defendant's submission to the government was false within the meaning of the Act. United States ex rel. K&R Ltd. Partnership v. Massachusetts Housing Finance Agency, 456 F. Supp.2d 46, 56 n.6 (“[The defendant] argues that its claims cannot be false because its interpretation of the notes, even if incorrect, was objectively reasonable. The reasonableness of [defendant's] interpretation goes to the scienter prong, not falsity”).

The Ninth Circuit correctly recognized the distinction between the knowledge and falsity elements of FCA liability in United States ex rel. Oliver v. The Parsons Co., 195 F.3d 457 (9th Cir. 1999), which reversed a district court holding that falsity was not established because the defendant demonstrated that it made a reasonable interpretation of an ambiguous accounting standard. Id. at 462-463. As the Ninth Circuit reasoned, the meaning of the regulations “is ultimately the subject of judicial interpretation, and it is [the defendant's] compliance with these regulations, as interpreted by this court, that determines whether its accounting practices resulted in the submission of a ‘false claim’ under the Act.” Id. at 463. The court also made clear that the reasonableness of the defendant's interpretation of the accounting standards, although potentially relevant to whether the defendant acted “knowingly,” was not relevant to the objective legal determination whether the submissions “were accurate in light of applicable law,” *i.e.*, whether

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<sup>1</sup> The mere existence of an ambiguity would not be relevant to scienter, however, if the defendant was unaware of the asserted ambiguity and did not rely upon it in good faith when submitting the claim. Cf. United States v. Tenet Healthcare Corp., No. CV-03-206 (C.D. Cal. Sept. 7, 2005) (“[e]vidence of others’ confusion over the coding standards does not tend to establish whether Tenet itself was confused by those coding standards, nor does it tend to show that Tenet’s interpretations of those standards was ‘reasonable’.”). Moreover, even a defendant that is aware of a possible ambiguity but does nothing to ascertain the proper resolution of that ambiguity prior to submitting a claim for payment may be found to have acted with “deliberate indifference.”

they were “false.” Id.

Similarly, in United States v. Mead 426 F.2d 118 (9th Cir. 1970), the Ninth Circuit correctly recognized the distinction in the False Claims Act between knowledge and falsity. In Mead, the defendant argued that the term “cost” as used in federal regulations and government forms was ambiguous, and that he had believed in submitting claims for payment that “cost” referred to market value rather than actual out-of-pocket expenses. Id. at 121-122. The Ninth Circuit held, “[b]ased on [its] construction of the applicable regulations and forms,” that the defendant’s submissions were false because “fair market value or actual value is not the correct measure of the cost of the projects.” Id. at 122. The court went on to hold that, although the claims were “false within the meaning of the False Claims Act,” the evidence failed to show that the defendant had the requisite degree of knowledge for liability. Id. at 123. In reaching this conclusion, the court emphasized that the case did not present “a situation where the meaning of government regulations or forms has long been established.” Id. at 124.

Thus, it is the proper provenance of the Court to determine whether the Defendant’s conduct is “false” for purposes of the FCA. This will necessarily involve an analysis of the appropriate statutes, regulations, Medicaid Rebate agreements, as well as the purposes animating the Medicaid Rebate program.<sup>2</sup>

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<sup>2</sup> In 1990, Congress reviewed the prices that Medicaid was paying for prescription drugs and determined that Medicaid routinely paid more than other large purchasers for prescription drugs. See H.R. Rep. No. 101-881, at 96 (1990), reprinted in, 1990 U.S.C.C.A.N. 2017, 2108.

Congress concluded that “Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on [brand name] drugs that other large public and private purchasers employ.” 1990 U.S.C.C.A.N. at 2108. Congress therefore decided to “establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser.”

(continued...)

### III. Any Dismissal Should be Without Prejudice to the United States

Defendants moved to dismiss relator's claims *inter alia* for failure to plead with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. The United States requests that if the Court dismisses relator's Fourth Amended Complaint under Rule 9(b), it should be without prejudice to the United States. Under the FCA, a relator files his complaint on behalf of the United States, and once the United States has notified the Court that it declines to intervene, the relator is free to pursue the case on his own. 31 U.S.C. § 3730. Under such circumstances, the United States does not file the complaint that initiated the action. Because the United States has no part in preparing such complaints, it should not be prejudiced if a relator has failed to plead the allegations sufficiently. Such a dismissal does not constitute a ruling on the merits, and does not mean that a better informed relator or the United States could not make out a viable claim in the future.

Moreover, a dismissal with prejudice would be unfair because a relator's complaint that is broadly drafted, if dismissed with prejudice to the United States, could be improperly argued by a defendant to have the preclusive effect of preventing future actions by the United States against

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<sup>2</sup>(...continued)

Id.; see also Pharm. Research & Mfrs. of Am. v. Thompson, 251 F.3d 219, 225 (D.C. Cir. 2001) ("Congress imposed the rebate requirement ... to prevent manufacturers from charging the government and taxpayers above-market prices for Medicaid drugs.")

All participants in the Medicaid Rebate Program must enter into Rebate Agreements with the Secretary of Health and Human Services. The Rebate Agreement provides that "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme," which, as demonstrated above, is intended to reduce costs by requiring that Medicaid receive the benefit of the prices offered by manufacturers to their customers. Rebate Agmt., IX(e). The Rebate Agreement also provides that, in the absence of specific guidance, a manufacturer may make reasonable assumptions in its calculation of AMP, "consistent with the intent of Section 1927 of the [Social Security] Act, Federal regulations and the terms of the Rebate Agreement." Id., II(I). Furthermore, those assumptions must be documented and maintained. Id.



the defendant. This is not in accord with the purpose of the False Claims Act qui tam provisions, which is assisting the United States in pursuing fraud, not hindering it, and should not be the result of the dismissal of an improperly pleaded complaint by a relator whom the United States does not control. See United States ex rel. Williams v. Bell Helicopter Textron Inc., 417 F.3d 450, 455 (5th Cir. 2005).


Accordingly, the United States submits that, if granted, any dismissal under Rule 9(b) should be without prejudice to the United States. If the Court dismisses relator's claims under Rule 9(b), it need not address Defendants' request that relator's claims be dismissed under Rule 12(b)(6).

#### IV. Conclusion

In sum, relator's allegations that the Defendants engaged in a fraudulent scheme that led to the under-reporting of AMP can state an actionable claim under the FCA, provided that the relator has pled sufficient facts to support that theory. The United States takes no position on whether the relator has adequately pled facts sufficient to support that theory here.

Respectfully submitted,

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Dated: June 15, 2012

  
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